UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,477	04/18/2001	Brendan Larder	VIP0011	8810

23377 7590 03/25/2005

WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE, 46TH FLOOR
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/836,477	LARDER ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,13,16-32 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,13,16-32 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 13 December 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-5, 8, 13, 16-32, and 39-41 are currently pending.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 recites "the method of claim 1, wherein the Human Immunodeficiency Virus comprises at least one of a virus". This does not limit claim 1, as HIV IS a virus. Correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26 and 27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In regard to claim 26, a report, per se, is non-statutory and is non-functional descriptive material. See MPEP 706.03(a), which states:

> For example, a mere arrangement of printed matter, though seemingly a "manufacture,"is rejected as not being within the statutory classes. See In re Miller, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); Ex parte Gwinn, 112 USPQ 439 (Bd. App. 1955); and In re Jones, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967).

In regard to claim 27, as computer-readable medium, comprising a phenotype is non-statutory subject matter, as it contains non-functional descriptive material. See MPEP 2106, which states:

> Abstract ideas, Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759, or the mere manipulation of abstract ideas, Schrader, 22 F.3d at 292-93, 30 USPQ2d at 1457-58, are not patentable. Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure"is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data. Both types of "descriptive material" are nonstatutory when claimed as descriptive material per se. Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized.
> Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. In re Sarkar, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978) ("[E]ach invention must be evaluated as claimed; yet semantogenic considerations preclude a determination based solely on words appearing in the claims. In the final analysis under 101, the claimed invention, as a whole, must be evaluated for what it is.") (quoted with approval in Abele, 684 F.2d at 907, 214 USPQ at 687). See also In re Johnson, 589 F.2d 1070, 1077, 200 USPQ 199, 206 (CCPA 1978) ("form of the claim is often an exercise in drafting").

Thus, nonstatutory music is not a computer component and it does not become statutory by merely recording it on a compact disk. Protection for this type of work is provided under the copyright law.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8, 13, 16-32, and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 recites "and the genetic sequence of the protease region and reverse transcriptase region". This is unclear because the protease region and the reverse transcriptase region are recited previously. Does Applicant intend that the genetic sequence be chosen from either just the protease region or just the reverse transcriptase region or the two together? This is an unclear Markush group. Clarification is requested.

Claim 39 recites "receiving a genetic sequence from the Human Immunodeficiency Virus from the patient". There is insufficient antecedent basis for "the patient" in the claim. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 8, 13, and 16-18, 23, 24, and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Boden et al. (JAMA (1999) September, Vol. 282, No.12, pages 1135-1141).

In regard to claims 1 and 28, Boden et al. teach obtaining a sequence of HIV from a patient sample (page 1136, column 2), identifying a mutation pattern (page 1137, column 2, results), searching a relational database (page 1137, column 1, sequence analysis), and determining a phenotype (page 1137, column 2).

In regard to claim 2, Boden et al. teach a series of phenotypic analysis based upon multiple therapies, such as protease inhibitors and reverse transcriptase inhibitors (page 1137, column 2).

In regard to claim 3, mutation patterns for zidovudine, for example, were found (page 1137, column 3).

In regard to claims 4 and 5, the samples were from HIV patient plasma samples (page 1136, column 1).

In regard to claim 8, mutations consisted of point mutations, for example (page 1138, column 2).

In regard to claim 13, the genetic sequence of HIV was from protease and reverse transcriptase genes (page 1137, column 1).

In regard to claim 16, mutations included more than one mutation for a therapy. For example, multiple resistance mutations existed in zidovudine-related resistance mutations (page 1137, column 3).

In regard to claim 17, the database searches of the HIV-1 use pairwise alignment, in which like sequences cluster together (page 1137, column 1).

In regard to claim 18, the mutations are found in HIV, for example in the protease and reverse transcriptase region of the *pol* gene (page 1137, column 2).

In regard to claim 23 and 24, fold-change is measured using 50% luciferase reporting (page 1137, column 2).

Boden et al. recite a report or computer readable medium, as indicated in claims 25-27 and 39-41. In addition, Boden et al. use the PhenoSense assay developed by Virologic in which reports are generated using computer systems (see example of the report called :Virologic HIV Assays:Review of Report Forms).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8, 13, 16-32, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boden et al. (JAMA (1999) September, Vol. 282, No.12, pages 1135-1141).

In regard to claims 1 and 28, Boden et al. teach obtaining a sequence of HIV from a patient sample (page 1136, column 2), identifying a mutation pattern (page 1137, column 2, results), searching a relational database (page 1137, column 1, sequence analysis), and determining a phenotype (page 1137, column 2).

In regard to claim 2, Boden et al. teach a series of phenotypic analysis based upon multiple therapies, such as protease inhibitors and reverse transcriptase inhibitors (page 1137, column 2).

In regard to claim 3, mutation patterns for zidovudine, for example, were found (page 1137, column 3).

In regard to claims 4 and 5, the samples were from HIV patient plasma samples (page 1136, column 1).

In regard to claim 8, mutations consisted of point mutations, for example (page 1138, column 2).

In regard to claim 13, the genetic sequence of HIV was from protease and reverse transcriptase genes (page 1137, column 1).

In regard to claim 16, mutations included more than one mutation for a therapy. For example, multiple resistance mutations existed in zidovudine-related resistance mutations (page 1137, column 3).

In regard to claim 17, the database searches of the HIV-1 use pairwise alignment, in which like sequences cluster together (page 1137, column 1).

In regard to claim 18, the mutations are found in HIV, for example in the protease and reverse transcriptase region of the *pol* gene (page 1137, column 2).

In regard to claim 23 and 24, fold-change is measured using 50% luciferase reporting (page 1137, column 2).

Boden et al. do not specifically teach that 50, 80, 90, or 100% of the database mutations are identical to said mutation pattern of the genetic sequence of the sample HIV, as in claims 19-22 and 29-32. However, it would have been prima facie obvious to one of ordinary skill in the art that depending upon the sample tested from an individual patient, and the sample set in the database, that the HIV sample could match the HIV database patterns. Boden et al. show that distance matrix evaluations are done on the phenotypic data, which would show relationships of samples to database entries. One would be motivated to investigate the relationships using this method.

No claims are allowed.

Conclusions

The rejections under 35 USC 112, first paragraph have been withdrawn in view of Applicant's arguments.

The rejections under 35 USC 103 over Harrigan et al. in view of Ioannidis et al. have been withdrawn in view of Applicant's arguments.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

March 14, 2005
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A Clow

MARJORIE A. MORAN
PRIMARY EXAMINER
Marjorie A. Moran
3/16/05